Clinical Islet Transplantation Consortium

PUBLICATION POLICY AND PROCEDURES

Version: 2.0

Version Date: September 1, 2015

Publication Policy & Procedures

Instructions for Principal Investigators and Lead Authors

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1. GUIDING PRINCIPLES

I) Terms

Chair: The individual responsible for the initial application submitted to the Clinical Islet Transplantation Consortium (CITC) Publication Committee

Lead Author: The individual appointed or invited by the Principal Investigator or, in cases when the proposed publication does not apply to only one protocol, by the publications committee (subject to the approval of the steering committee) who will coordinate the development, revision and submission of a publication arising from a CITC study (note that often this will be the chair). The lead author will organize an appropriate writing group that is representative of those contributing to the conception of the paper and will be responsible for preparing and submitting the publication.

Clinical Islet Transplantation Consortium Publication Subcommittee (PSC): Appointed by the CITC Steering Committee, the publication committee acts as the primary body overseeing the publication and release of CITC information.

Clinical Islet Transplantation Consortium: A collaborative research group organized to study methods to improve islet transplantation in Type I diabetes and to achieve licensure for the procedure in the United States.

DAIT: Division of Allergy Immunology and Transplantation, of the National Institute of Allergy and Infectious Disease (NIAID), of the National Institute of Health (NIH)

DDEM: Division of Diabetes, Endocrinology, and Metabolic Diseases of the National Institute of Diabetes, Digestive, and Kidney Disease (NIDDK), National Institute of Health (NIH)

DCC: The data coordinating center at The University of Iowa acts as the Data Coordinating Center for the Clinical Islet Transplantation Consortium.

Publication: Any manuscript or abstract for scientific audiences, not including communications with the media, such as press releases or interviews.

It will be accepted by all participants that the study principal investigator and chair, where different, will work to reach consensus on matters affecting publications such as assignment of lead authorship and general authorship, selection of appropriate journals/conferences for presentation, etc.

II) Purpose of the Publications Subcommittee

The Clinical Islet Transplantation Consortium Publications Subcommittee (PSC) acts as the primary body overseeing the publication and release of CITC information. The PSC functions to set CITC publications policy, monitor, assess and facilitate the timely publication of CITC results and mediate any disputes arising over the publication/presentation of CITC results.

The goals of the CITC Publications Subcommittee are:

1) To promote timely and high-quality presentation and publications from CITC studies.

2) To support broad and equitable participation by CITC investigators in presentations and publications.
3) To provide editorial support and timely review for presentations and publications.
4) To ensure that publication proceeds in a fashion consistent with academic norms, adhering to the practice of presenting complete data to the public only after it is published in a peer-reviewed journal or through abstracts presented at scientific meetings.

III.) Publications Subcommittee Composition

The CITC Publications Subcommittee (PSC) will consist of the voting members of the Steering Committee or their designee (see Appendix 2) The PSC members will be appointed by the CITC Steering Committee. The CITC PSC members will serve for the duration of the funding of the CITC.

The PSC members will serve voluntarily. With proper notification to the PSC Chair, a member may resign from service at any time. It is the responsibility of the CITC Steering Committee to appoint new or additional PSC members.

IV) Confidentiality of Reviews

Manuscripts and abstracts submitted to the CITC PSC for initial and subsequent review will be held in the strictest confidence and will not be shared with any individuals except for those directly involved in the manuscript review process.

V.) Conflicts of Interest

The PSC members will disclose all conflicts of interest they may have prior to committee review and discussions regarding materials presented to the PSC. When appropriate, a PSC member will be excused from reviewing and discussing materials in which a disclosed conflict of interest exist. It is the responsibility of the CITC Steering Committee to appoint an alternate, if necessary.

VI.) Scope of Guidelines

1) These guidelines will apply to original manuscripts (including methodology, validation, laboratory approaches, etc.), abstracts, oral and poster presentations, letters to the editor, meeting proceedings, extended abstracts that include data collected as part of the CITC project, and reviews that include original CITC study data not previously published in a primary source.
2) These policies remain in effect even after formal conduct and funding of the CITC trials are complete.
3) For purposes of publications and presentations, all data derived from a single center CITC study or from specimens collected during that study are the collective intellectual property of the study chair(s), not those of any individual investigator, collaborating investigator, or the study sponsors from government and industry. All data derived from a multicenter study or from specimens collected during that multicenter study are the collective intellectual property of the consortium steering committee.

VII.) Ownership Data

It is an overriding principle with respect to data generated by the CITC that data collected in a single center study are the collective intellectual property of the study chair(s) unless otherwise stipulated by prior agreement with industry. Similarly, all data generated by a CITC multicenter trial are the property of the CITC steering committee. To facilitate the publication process in the collaborative environment of the CITC, investigators will agree to abide by these guidelines for the publication or public presentation of data, in whole or in part.

Investigators should note that, consistent with CITC's guidelines for collaborating industrial partners and NIH policy, an additional 60 day delay in publication may be requested in order for the investigators to file a patent related to the study described in the publication.

VIII) Data Sharing

The DCC will assume a leadership role to ensure that research results and related data are rapidly made available to other researchers, policymakers, and the general public as appropriate and as approved by the Steering Committee. The DCC will create a two-tiered application process overseen by the Steering Committee to make data archives and data enclaves available to qualified applicants with legitimate need through a restricted access component of the CITC website. The application will include a detailed description of the purpose of the proposed study, the specific data being requested, and a detailed description of the data analysis to be performed.

Data collected for the CITC will be made available to outside investigators subject to the Steering Committee's approval. Such data will not be provided for on-going blinded studies where release of the data would impact the performance of studies objectives. De-identified data sets will be made available with the following restrictions:

> **Data Archive**: will be fully de-identified data set in which all HIPAA-defined individual identifiers are removed, which may be suitable for many types of exploratory data analyses. A confidentiality agreement will be signed by the investigator stipulating that only those individuals named in the application will have access to the data, no copies may be made of the data, no efforts will be made to identify individual cases, and archive data will not be linked to other identifiable data. If this data is used for publication, acknowledgement of its source will be required.
>
> **Data Enclave**: will be HIPAA-defined limited data sets, in which certain additional data elements are included which could be used, with some probability, to identify the individual. Access to data enclaves will require substantially more justification than that required for access to stat archives, including specifically why the investigator requires the additional data elements for study. A confidentiality agreement similar to that described for data archive will be required, except that the investigator will also agree that any potential publications be first submitted to the SACC for disclosure limitation review. In addition, the investigator will enter into a formal HIPAA-compliant data use agreement that, in addition to containing the terms of the confidentiality

agreement, also describes the investigator's procedures for safeguarding the data enclave and its associated files.

IX) Rapid Dissemination of Clinical Islet Transplantation Consortium Research

The goal of these policies and procedures is to publish in a fashion consistent with academic norms, adhering to the practice of presenting complete data to the public only after it is published in a peer-reviewed journal or through abstracts presented at scientific meetings. Exceptions may occur in order to allow rapid release of clinical trial results in order to disseminate information that is of public health importance. Such exceptions may be authorized only by the CITC Steering Committee.

X) Authorship & Responsibilities of the Lead Author

The Clinical Islet Transplantation Consortium is committed to ensuring fair and equitable acknowledgement of all scientists contributing to each research project and recognizes the right of all authors to review manuscripts before submission.

Prior to beginning to prepare a publication, the group interested in participating will decide on a lead author and the author list. This will be done on a publication by publication basis and the members of the publication group should be determined in a manner that is equitable to all who are participating in the study. Where appropriate, the group should include a representative from the DCC.

The Lead Author is expected to make available to all co-authors a draft of each manuscript, abstract, revision and/or review comments in sufficient time for comments to be returned to him/her and appropriate modifications to be made before submission. The lead author must also ensure that all co-authors have had an opportunity to review and comment upon author lists of planned submissions before the Study Leader submits a request to publish to the PSC.

The Lead Author will agree to file with the DCC, all necessary CITC forms, copies of first, final and revised manuscripts and supporting materials, correspondence with journal editors on materials pertaining to the manuscript in question and article reprints.

All Site Investigators, including the Study Leader, are expected to refer to DAIT/DDEM and the Project Officer, and their respective institution or organization for guidance and instructions in the interpretation of terms reflected in all fully executed Clinical Trial Agreements and the CITC Subcontract.

XI) Cooperation with Industry

CITC is aware of the need to protect proprietary interests of academic/industrial partners. Clinical Trial Agreements (CTAs) with collaborating companies/institutions that agree to supply their proprietary materials, such as drugs and biologics, to member institutions of the Consortium will be negotiated by the awarding agency, NIAID/NIDDK, on behalf of the CITC and its investigators. The ability of participating investigators and their respective institutions to fully participate in CITC will likely depend upon the investigator's and Subcontracting Institution's ability to offer these necessary rights or options that are attractive to commercial providers of proprietary materials.

It is the expectation of CITC that the negotiated CTAs will contain a publications clause that will, upon the request of the industrial partner, delay submission of manuscripts/abstracts to ensure that associated intellectual property rights can be protected. Consistent with current industrial operating standards and NIH policy, it is expected that such publications delays would not exceed 90 days: industrial partner has 30 days from time of submission of draft manuscript/publication by study leader to determine if a patent is going to be filed; after this first 30-day delay, if a patent will be filed, the industrial partner has an additional 60 days to file the patent. Although these timeframes are goals within CITC, the negotiated terms of the Clinical Trials Agreement, as outlined in the Terms of Award of the Subcontract Agreement from DAIT/DDEM shall supercede the timeframes outlined in this policy and shall be the governing terms of award. A copy of the final executed agreement will be forwarded to the Investigator by the awarding agency.

It is standard practice that publications arising from CITC studies, where industry participation is involved, may not disclose any confidential or proprietary information unless prior authorization is granted by owner of such information.

Note that supplemental agreements between a Study Leader and an industry partner that affect publication of results from CITC research studies may be entered into only upon the authorization of the Steering Committee and NIAID/NIDDK.

2. PREPARING AND SUBMITTING MANUSCRIPTS

1. **Following initial analysis of the study data**, in anticipation of publication, the study chair will forward a "**Publication Notification**" form to the DCC (Appendix I). Submission of this form will allow the CITC PSC to anticipate publications, provide writing and editing assistance and allow for speedy review. This form describes: working title, list of authors, a synopsis of the results and the conclusions to be contained in the manuscript, a timeline for submission and other simple information.
2. **All manuscripts and publications** must be approved by the Steering Committee. The Steering Committee will respond within three working days of its being notified. Otherwise it can be assumed that the abstract or publication has been approved.
3. **During manuscript preparation:** DCC statisticians and the PSC will be available to authors to assist in analysis and copy editing, subject to prioritization guidelines (Section 6 below). Note that it is expected that the Lead Author will maintain communication with other authors during development and solicit input wherever necessary.
4. **Upon completion of the first draft**, the Lead Author must forward a complete copy (with figures and references) to the DCC and all listed authors. The DCC will forward copies to the PSC, who will provide their comments **within 10 business days (2 weeks) to the Lead Author**.
5. After PSC review, the PSC Chair will send the manuscript, along with the committee's final decision, to the Steering Committee Chair.

- A minority vote (≤7 out of 15 members) for approval will result in a rejection from the PSC.
- A majority vote (≥8 out of 15 members) will result in approval from the PSC.
- In the event of a tie, the NIH Project Officer will cast the deciding vote.

6. The NIAID/NIDDK Project Officer will review all requests for publications. The NIAID/NIDDK Project Officer has the authority to deny any request for publication.
7. If the PSC requested revisions or a response from the Lead Author, then the Lead Author should revise and resubmit to the PSC Chair.
8. Once the final draft has been approved by the CITC Publications Subcommittee and there is no objection from the NIAID/NIDDK Project Officer, authorization to publish will be granted once all authors and industry partners have documented their approval of the final draft, as below.

    - **Sign-off by all authors**: Prior to final CITC PSC authorization, all authors named on the manuscript must forward a completed "Author Agreement Form" to the CITC PSC that confirms they have reviewed and approve of the manuscript and details individual authors responsibilities.
    - **Sign-off by industry partners:** If the study from which the manuscript was derived involved a CTA with one or more industrial partners, the CITC PSC must receive a completed "Manuscript Approval Form" from the designated individuals from each company, as detailed in the original CTA.

    Once sign-offs have been received by the CITC PSC, the lead author will be notified of CITC PSC authorization and may then proceed with submission of the manuscript to the journal.

    Note: The CITC will not authorize publication until "Author Agreement Forms" have been received by all authors.
9. **Upon receipt of Journal Proofs**, the Lead Author will agree to forward his/her annotated copies to the DCC at the time of submission to the journal.
10. **Upon publication of the manuscript**, the DCC will forward to the Steering Committee the complete reference of the article and at least one original reprint of the article. The publication will be presented at the following face-to-face Steering Committee meeting.

Note: All manuscripts must contain the following sentence within the acknowledgements section:

- *"This research was performed as a project of the Clinical Islet Transplantation Consortium, a collaborative clinical research project headquartered at the (NIH Institute)."*

3. SUBMISSION TO PUBMED CENTRAL

Beginning May 2, 2005, NIH-funded investigators are being asked to voluntarily submit accepted, final versions of manuscripts to PubMed Central (PMC). PMC is the NIH digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research journals. It is a publicly-accessible, permanent, and searchable electronic archive available on the Internet at http://www.pubmedcentral.nih.gov/.

The NIH policy applies to any manuscript arising, from research supported in whole or in part, with direct costs from NIH.

More information on the NIH Public Access Policy is available on the web.

4. PREPARING AND SUBMITTING ABSTRACTS

1) Upon completion of a preliminary draft of the abstract, the Lead Author must forward a copy to the DCC and all listed authors, **within 10 business days of the abstract submission deadline.** The Lead Author of an abstract will submit an "Abstract Notification" form (Appendix II) to the DCC.
2) The DCC will forward the PSC members a copy of the abstract submission upon receipt.
3) The PSC will meet by teleconference **within 5 business days** to review the abstract.
4) Within 48 hours of the review, the PSC Chair will send the abstract submission to the Steering Committee, along with the committee's final decision.
    - A minority vote (≤2 out of 5 members) for approval will result in a rejection from the PSC.
    - A majority vote (≥3 out of 5 members) will result in approval from the PSC.
5) The NIAID/NIDDK Project Officer will review all requests for publications. The NIAID/NIDDK Project Officer has the authority to deny any request for publication.
6) When the Lead Author receives confirmation of abstract acceptance or denial from the meeting organizers, he/she must notify the CITC PSC of the result together with date, time and session information (including whether poster, plenary talk, symposium talk, etc) for the abstract.
7) **Upon publication of the abstract,** the DCC will forward to the Steering Committee the complete reference of the abstract and at least one original reprint of the abstract.

Note: All abstracts must contain the following sentence within the acknowledgements section:

- *"This research was performed as a project of the Clinical Islet Transplantation Consortium, a collaborative clinical research project headquartered at the (NIH Institute)."*

5. DISPUTE RESOLUTION

In all disagreements and disputes relating to the publication of CITC related research materials, every effort should be made to resolve the issues amongst the relevant parties.

In those cases where consensus agreement cannot be reached through this process, a written request may be forwarded to the Chair of the Steering Committee for immediate review by the CITC Steering Committee.

6. PRIORITIZATION

All prioritization issues will be addressed in an on-going basis by the CITC PSC. Examples where the CITC PSC may intervene include, but are not limited to:

- Instances where non-ignorable content overlap exists between multiple manuscripts.
- Instances where an "excessive" lag in communication has occurred between the lead author and either the CITC PSC or the DCC.
- Instances where the demand for statistical support exceeds the DCC's capacity.

The CITC PSC will work towards the resolution of competing manuscripts, whether it is due to overlapping content or competing demand for CITC resources, such as statistical support. The DCC may prioritize statistical support based on the completeness of the documents specified in Section 1.8 above, with special emphasis on the analysis plan.

Additionally, prioritization may also occur in the event of an excessive lag in communication between the lead author and either the CITC PSC or the DCC. The definition of "excessive" will be adapted on a case-by-case basis. As guidance, a lag of 6 months from the last correspondence between the lead author and either the CITC PSC or the DCC shall, under usual circumstances, be deemed "excessive". Excessive lags in communication can lead to CITC PSC action, including the assignment of a different lead author.

Appendix I: Publication Notification Form

Clinical Islet Transplantation Consortium **Publication Notification From**
Working Title:
Lead Author:
Contributing Authors:
Synopsis of Results and Conclusions:
Timeline for Submission:
Comments:

Appendix 2: Voting Members of Publication Subcommittee

Eric Foster

Bernhard Hering

Dixon Kaufman

Bo Nilsson, designee for Olle Korsgren

Xunrong Luo

Jim Markmann

Andy Posselt

Nicole Turgeon

Ali Naji

Jose Oberholzer

Rodolfo Alejandro, designee for Camillo Ricordi

James Shapiro

Nina Luning-Prak

NIH Medical Officer